Corrective/Preventive Action and Root Cause/Data Analysis Seminar

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Learning Objectives

- Help you get the most out of your corrective actions and ensuring corrective action responses meet requirements.
- Strengthen your understanding of the root cause analysis process
- Clarify the difference between Corrective and Preventive Actions
  - Highlight areas to leverage off of to identify opportunities for preventive action
- Emphasize the importance of data analysis, ensuring your data analysis efforts are value-added and how to utilize your data analysis in preventive actions.
- Clarify how this all works as a system.

Overview

Time	Activity
9:00 – 9:15 am	Introductions
9:15-10:15 am	Opening Discussion/Participant Input Audit Value and Momentum Corrective Action CA Challenges CA Components Typical CA Process Flow Importance of CAs Preventive Action Data Analysis GSFC CA/PA Process
10:15-10:30	Break

Overview (Cont'd)

Time	Activity
10:30 – 10:50 am	CA Exercise: Work in Groups
10:50 – 11:15 am	CA Exercise Presentations
11:15 – 11:45 am	EaglePicher presentation by Forrest Reed: A supplier's story of improving corrective actions.
11:45 am – noon	Wrap-up Discussion

Audit Value and Momentum

Audit Value and Momentum

- Much of the audit value occurs prior to the arrival of the audit team – in the efforts the organization puts into preparing for the audit.
- Audits often result in the identification of issues that require attention.
  - Too often audits result in a frenzy of activity to respond to the audit with band aide fixes or worse, no real activity.
  - This is where a strong corrective action program is critical!
    - Don't let the process end when the band aide is put on.

Audit Value and Momentum

- Do you think your organization/audit program is capitalizing on the momentum gained and the increased management attention resulting from the audit?
  - At the time of the outbrief, there is a lot of management and organizational attention on the noncompliances.
  - Often audit timelines result in losing the momentum that results from audits.

Corrective Action

CA Challenges

Not bringing in the right group

Problem not well defined

Focusing on people or retraining only

Culture

Not truly understanding the problem or its cause

Lack of containment actions

Stopping at Quick Fixes

Management Commitment

Resource Balancing

Impact/Scope not understood

CA Challenges (Cont.)
Example GSFC Supply Chain Findings Related to Corrective/Preventive Action Process

Supplier's Corrective Preventive Action Request form does not identify criteria for **root cause analysis**.
Determination and implementation of action taken by Supplier do not effectively provide **root cause analysis or corrective and preventive actions**. Repeat finding from 2009 Card #'s 12 & 13
Open Corrective Action Requests are averaging **180 days since inception**, which violates industry and internal requirements for timely closure of corrective actions.
The root cause corrective action system is not effectively addressing the many QMS performance parameters and the **many corrective actions that are past due** (Reissue of 2011 Finding NC-014). Eight (8) of the fifteen (15) findings from the NASA June 2011 assessment had not been resolved.
Corrective Actions are not timely because the average delinquent corrective action is currently 100.8 days. (repeat of Card #020 from the OCT 2011 assessment)
No evidence of the **incorporation of identified lessons learned** into applicable work processes.
There is **no process in place to perform EEE Part Failure Analysis**
Failure Analysis Report was approved as closed with no evidence that a review of the effectiveness of the corrective actions taken was done.
Corrective and Preventive Action processes are not effectively implemented. **Four nonconformance reports were randomly sampled and none included root cause analysis or planned corrective action**.

CA Challenges (Cont.)

- Many corrective action responses to audit findings do not address:
  - How the process failure was addressed (some focus only on a nonconforming product identified) (reference AS9100C & ISO 9001:2008 8.2.3)
  - What was specifically done to address the nonconforming product identified (some only focus on the process and forget to address the nonconforming product identified) (reference AS9100C & ISO 9001:2008 8.3)
  - Looking across the organization for other areas where the nonconformity may occur and applying preventive actions in those areas (AS9100C & ISO 9001:2008 8.25.3)

CA Components

- CA Response Components
  - Immediate Action
  - Root Cause Analysis
    - Root Cause Tools and Methods
  - Scope Investigation
  - Corrective Actions - Fix Cause(s)
  - Evaluation of Effectiveness

CA Components (Cont.)

Immediate Action (remedial, containment action)

- The action planned or taken to correct the specific individual problem or condition that was found to be a nonconformity.
  - For example, immediate action a supplier might take if expired Inspection, Measuring and Test Equipment (IM&TE) were identified in their testing lab would be to remove the IM&TE from use (segregate/turn in to Cal lab/etc.).
- Should include actions required to contain the immediate problem.
- May include notification of the customer or others potentially affected as appropriate.

CA Components (Cont.)

Root Cause Analysis

- Root Cause Analysis: *Defined analytical method(s) employed to identify and understand the cause(s) of an undesired outcome or nonconformance in order to formulate appropriate corrective action(s) that will prevent the recurrence of the undesired outcome or nonconformance throughout the organization. Root cause analysis is used also to identify and understand the cause(s) of a potential undesired outcome or nonconformance in order to formulate appropriate preventive action(s) that will prevent the occurrence of the undesired outcome or nonconformance throughout the organization. In addition, root cause analysis is used to determine if the cause(s) and associated real or potential undesired outcome or nonconformance are isolated or systemic*
- *Root Cause(s): events, factors or conditions that if eliminated or sufficiently mitigated through appropriate action(s) would prevent the recurrence or potential occurrence of an undesired outcome or nonconformance throughout the organization.*

CA Components (Cont.)

Root Cause Analysis

- Root Cause Analysis efforts on flight project problems frequently do not go far enough to expose root cause(s)
- Often the underlying organizational factors of a problem (e.g. training, process, infrastructure, etc.) are not addressed

CA Components (Cont.)

Root Cause Analysis

- There are numerous problem and cause analysis tools available to apply to problems
  - What tool/method should you apply?
    - Action Decision Table
    - Change Analysis/No Problem Comparison
    - 8 Discipline (8D) Problem Solving
    - Events and Causal Charting
    - Failure Mode Effect Analysis
    - Fault Tree Analysis/Causal Tree
    - **Fishbone Diagram**
    - Storytelling/Analogy
    - **5 Why?**
    - Other?
  - When conducting CA, do you ensure you have someone involved that is competent in CA and the CA models used within your organization?

CA Components (Cont.)

Root Cause Tools and Techniques: 5 Why

Asks the question…

Why?

….enough times to find the root cause(s). In the course of asking why, you will find many causes…

CA Components (Cont.)

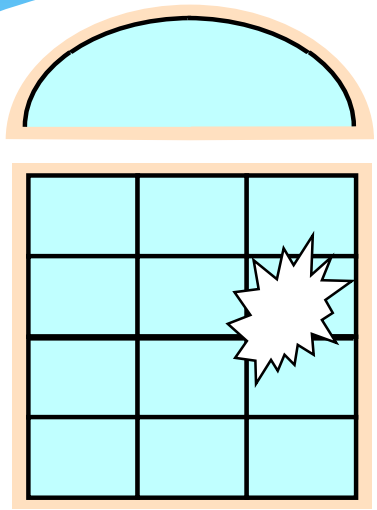
Root Cause Tools and Techniques: 5 Why

- ***5 Why helps to turn the Undesired Outcome into an Event Question***
  - An Event Question should be:
    - Short
    - Simple
    - Concise
    - Focused on One Problem
  - An Event Question does not:
    - Tell what caused the event
    - State what to do next

"If you cannot say it simply, you do not understand the problem"
- Albert Einstein

CA Components (Cont.)

Root Cause Tools and Techniques: 5 Why



The Event Question:
Why did the window break?
Not:
Who threw that baseball?
OR Don't give the bat to Timmy

The Event Question:
Why was the Test Equipment calibration label exceeding its due date?
Not:
Who owns this Test Equipment?

CA Components (Cont.)

Root Cause Tools and Techniques: 5 Why

- There could be more than one "Why" path
  - Why is CA not timely?
    - It takes two weeks to assign it to the managers once issued
      - Why is it taking to weeks to assign it to Managers
    - Managers are provided six months to respond
      - Why are managers given 6 months to respond?

CA Components (Cont.)

Root Cause Tools and Techniques: 5 Why

- Data Collection - Items to be considered:
  - Location (Where)
  - Names (Who)
  - Roles/Functions
  - Time (When)
  - Conditions (operating/environmental)
  - Instructions (How)
  - Equipment
  - Physical Evidence
  - Recent Process Changes
  - Degree of Training

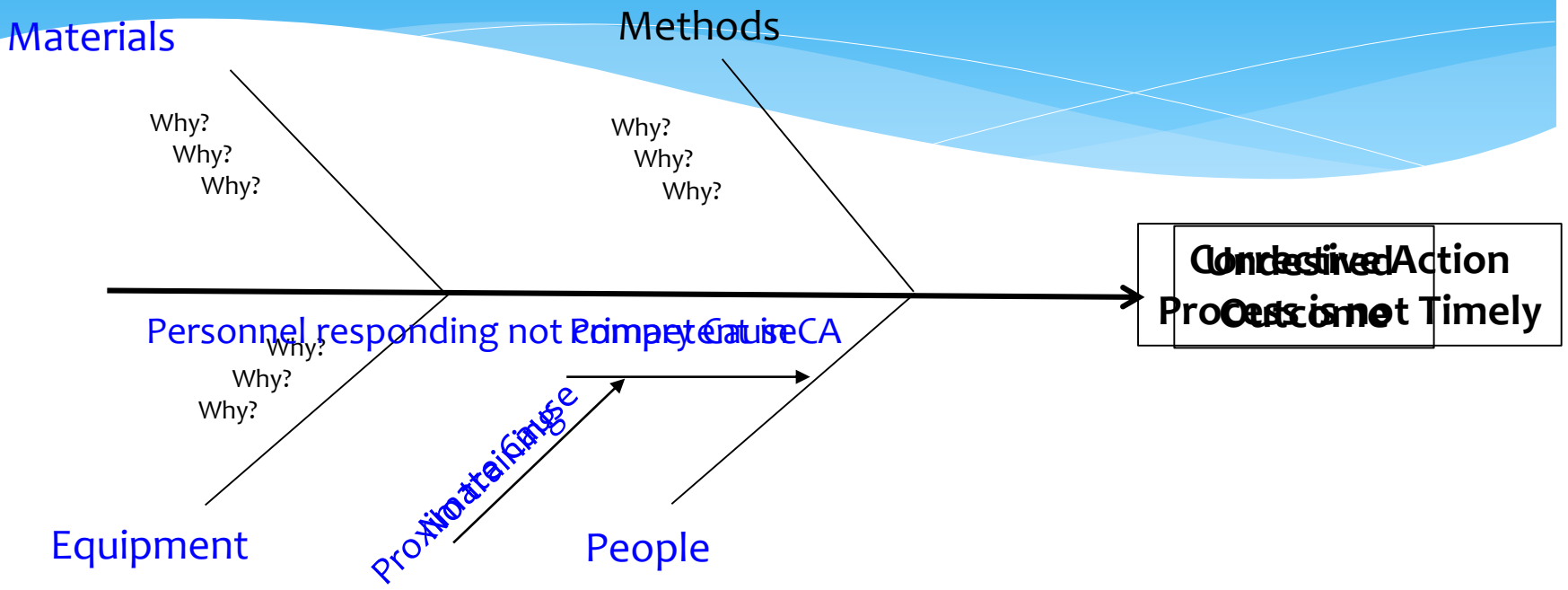
CA Components (Cont.)

Root Cause Tools and Techniques: 5 Why

- Don't forget to ask….what role did organizational factors play?
  - Policies and Procedures
  - Resource constraints
  - Processes
  - Infrastructure
  - Systems
  - Operating Instructions
  - Training
  - Management Processes
  - Culture
  - Others…

CA Components (Cont.)

Root Cause Tools and Techniques: Fishbone Diagram



- Brainstorm all relevant factors and group into categories
- Depict the possible causes graphically
- Ask Why? You can modify categories as necessary
- Take actions to address causes
- Methods can also be broken out into Management, Environment, and Process

CA Components (Cont.)

Scope Investigation

- In conjunction with the the cause analysis, investigate and determine the full scope (total population) of the problem or noncompliant condition.
  - Using the calibration example from earlier, an appropriate scope investigation would be to determine if the expired IM&TE were used since they expired, and if so what the potential impacts are. Additionally, the Center should review an additional sample of IM&TE across the Center to determine if expired IM&TE exists elsewhere. If so, determine if those items have been used since expiration and the potential impact.
- Scope investigations include evaluating related work and/or other processes for similar problems.
- Remember, additional Immediate Actions will need to be taken to correct any other problems or noncompliant conditions identified during the scope investigation.

CA Components (Cont.)
Corrective Action (Fix Causes)

- It's not enough that we know the cause(s) and the scope, now we have to fix the cause(s)
- The fix for the cause(s) needs to be:
  - Appropriate for the magnitude and the risks of the problem
    - Impacts to cost and schedule assessed.
  - Bounded:
    - Clear understanding of what is being fixed
    - Is the scope across individual, group, section, project, etc.?
    - *"Whys"* needs to be answered
  - Documented
  - Implemented in a timely manner
  - Effective: It prevents recurrence of the problem, over time
  - Evaluated for effectiveness

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Corrective Actions
  - The actions planned or taken at the system or process level, based on cause analysis and scope investigation, in order to prevent recurring problems or noncompliant conditions.
    - Ensure corrective actions address the causes and associated processes.
    - Ensure corrective actions go beyond fixing the immediate issue (the correction, where appropriate).
- Correction
  - Repair, rework or adjustment relating to the disposition of an existing nonconformity.

- So…..*corrective action* relates to eliminating the causes of the nonconformity, while *correction* relates to fixing the existing nonconformity

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Possible solutions to the identified causes should be identified and evaluated. When proposing the possible solutions, be open-minded. If multiple options are considered, an informed decision can be made to select the best solutions from the possible solutions.
- Areas to consider:
  - Change the Process
  - Documentation & Records
  - Education & Training
  - Written Communication
- Once a solution has been selected, an action plan with owners and due dates should be defined.

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Fixing the Causes: Change the Process
  - Understand the process by flowcharting it
  - Clarify, re-order or restructure the process
  - Drop non-value added steps from the process
  - Attempt to mistake-proof the process
    - May include a change in product design
  - Periodic evaluation by manager, supervisor, or technical expert
  - Form an on-going technical or business advisory group across Divisions/directorates where beneficial
  - Set up metrics to drive the right actions in the process

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Fixing the Causes: Documentation & Records
  - Update or create documents where needed
    - Project documentation
    - Requirement documents
    - Procedures
    - Specifications
    - Handbooks and Guidelines
    - Forms/templates
  - Submit updates to Flight Project Practices or Design Principles

CA Components
Corrective Actions (Fix Causes)

- Fixing the Causes: Education & Training
  - Infuse your solution into institutional training as appropriate:
    - Lab Manager Training
    - Quality Management Training
    - Specific Branch/Project Training
    - Safety Classes
    - Other Human Resource classes
  - Local training
  - Mentoring
  - Staff meeting, Group meeting, Group awareness briefings
  - Provide recurrent training where needed

CA Components (Cont.)
Corrective Actions (Fix Causes)

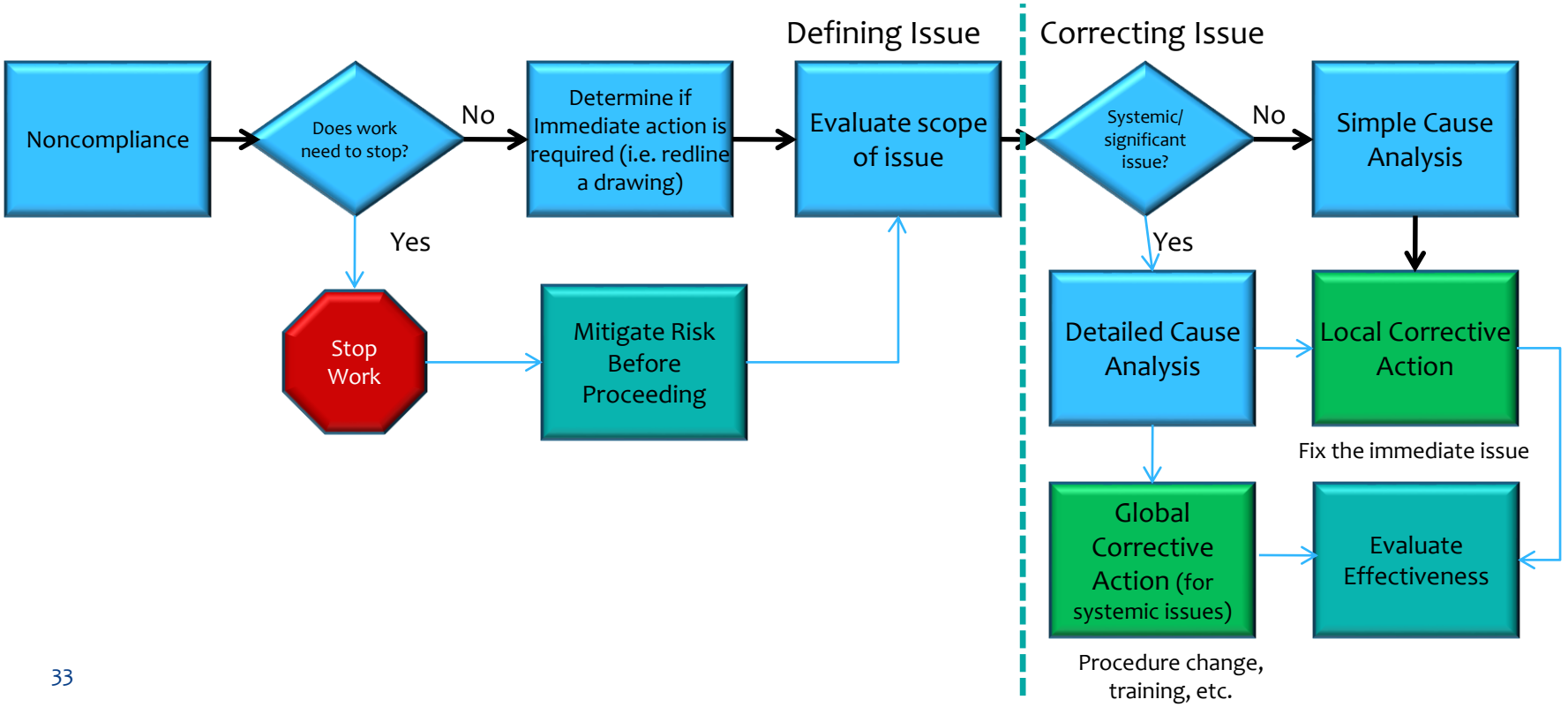
- Corrective Actions (Cont'd)
  - Fixing the Causes: Written Communication
    - Awareness e-mails
    - Directive e-mails
    - Notice from System Safety to Mission Assurance Managers
    - Group wide, Section wide, and/or Division wide memos
    - Cross Directorate to technical specialists
    - Management

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Evaluation of Effectiveness
  - Provides the information necessary to examine how well corrective actions are being implemented and to determine whether the corrective actions are achieving desired results
    - Requires run-time and re-evaluation
    - Key questions to ask:
      - Is objective data available to prove that actions taken work?
      - Has enough time elapsed to prove the Issue is truly fixed?
      - Since solutions were implemented, has the Issue been seen again?
      - What efforts have been made to track and report recurrence of the Issue?
      - Is sufficient evidence available in a presentable format to prove solutions are working?
      - Has the team looked for proof that the fix is working as planned?

CA Components (Cont.)
Corrective Actions (Fix Causes)

- Not all Nonconformance/Noncompliance are created equal
- Keys are the nature of finding (major/minor), and scope (systemic or not systemic)
  - Isolated findings should follow the "easiest" path along black arrows
  - Proper scope assessment determines if isolated, and should be stated as such in CA



Importance of CAs

- The full value of audit programs cannot be realized if the auditee does not adjudicate the noncompliances identified and prevent recurrence of the noncompliant conditions.
- CA plans coupled with audit results can aid management in their decisions – enables management by fact!

Preventive Action

Preventive Action

- The problem is not there yet… but there is potential
- Defined "action to eliminate the cause of a potential **nonconformity**… or other undesirable potential situation"
  - Example: Styrofoam cups found *near* ESD controlled area
- Preventive action opportunities may be derived from risk management, error proofing, failure mode and effect analysis (FMEA), and information on product problems reported by external sources.

Data Analysis

Data Analysis

- We have a tendency to take a lot of data, but how are we utilizing that data?
  - ISO 9001, paragraph 8.4 requires organizations to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.
- Data collection takes time and resources and metrics drive behavior.
  - We need to ensure that our data collection/metrics efforts are driving the correct behavior and are being utilized effectively.
- We have talked about different places to employ data analysis:
  - Cause Analysis
  - Scope Investigation
  - Corrective Action
  - Preventive Action

GSFC CA/PA Process

GSFC Finding Documentation

- The entire process is guided through Meta (a NASA Information System)
- After an audit (Internal)/assessment (Supplier), GSFC will document findings into Meta, and categorize them into a into one of the three categories below

Type of Finding	Definition	Corresponding Action
Nonconformance	Non-fulfillment of a requirement	CA Plan (includes root cause analysis and projected implementation completion date)
		CAs taken including effectiveness verification and supporting objective evidence
Observation	An opportunity for improvement and/or avoidance of a potential nonconformance	Investigation, input to Preventive Action process, disposition, and plan as applicable.
		For items that were dispositioned as Preventive Actions, action taken including effectiveness verification and supporting objective evidence
Positive Comment	Strengths, best/good practices, improvements	Consideration. Can be good source of data for customer feedback/analysis

GSFC CA/PA Process

- Once the finding is entered entered a Corrective Action Plan is due (Suppliers have 30 days)
  - The corrective action plan includes information on root cause analysis
- Once the finding is closed and your organization verifies implementation is effective, closure is reported to GSFC.
  - This information is uploaded to the Meta database.
- After submission the Lead Auditor (Internal) or Supply Chain Manager (SCM) (Suppliers) will review information submitted, coordinate with Subject Matter Experts, including project personnel, as applicable, and provide feedback.
- When a finding is determined as closed (internal) or after all findings that require response are reported as closed (Supplier), the follow-up method is determine by the Lead Auditor (Internal) or Supply Chain Manager (SCM) (Suppliers).
  - Follow-up will always be performed for Suppliers (either via a desk assessment or a physical assessment).
  - Additional follow-up for internal audits is at the discretion of the Lead Auditor.

Exercise

CA Response Exercise

- The examples we are going to hand out contain real examples of audit findings and corrective actions.
- We want to solicit your input on the adequacy of the content of the the CAs.
  - What additional items should have been considered in the CA?
  - What do you think the possible effects of the noncompliances are?
  - Were containment actions identified and appropriate?
  - Was scope/impact properly reviewed?
  - Was root caused addressed?
  - Is it evident that the CA was effective?
- Please work in groups and be prepared to have someone present for your group.

Example 1 – Finding Details

- Management System Documents A and B do not ensure the transportation department's calibration processes are in full compliance with requirements in Document X.
  - No reference to Document X was noted, nor was there full assurance that the current calibration vendor meets the organization's minimal calibration requirements.

Example 1 – CA

CORRECTIVE ACTION

- Initial Action: The existing list of items requiring calibration was updated to include items not on the list and to reflect whether they were Category 1 or 2 items. This list was submitted on 9/30/11 to the Calibration Manager so that the items could be included in the calibration program.
- Root Cause: Management of the calibration process for the transportation organization was split between multiple people in supply and transportation who did not coordinate with each other. Additionally, the people were not adequately knowledgeable of the requirements in the procedure.
- Cause Code: Inadequate training/certification

Example 1 – CA (Cont'd)

CORRECTIVE ACTION (Cont'd)

- Planned Action to Correct Root Cause: The Transportation Department will manage the calibration process for its equipment. This calibration process will be documented in Document A (completed 9/28/12). All items will be managed using the organization-wide calibration program (completed 2/13/13). The program will ensure that vendors providing calibration meet organization requirements.
- Estimated Corrective Action Completion Date: 10/15/2012
- Action to Correct Root Cause: The calibration process for the Supply Department's project logistics was documented in Document A on 9/28/12. Training on this document was completed 10/17/12. All corrective actions are believed to have been completed as of 10/17/12.
- Estimated Corrective Action Verification Completion Date: 02/08/2013

Example 1 – CA (Cont'd)

CORRECTIVE ACTION EFFECTIVENESS

- Verification: A review of the implemented processes was conducted on 1/24/13 to verify that they are being followed. One discrepancy was noted. Category 3 IMTE was not identified and included in the program. An additional verification will be conducted once Category 3 IMTE is included in the program. The additional verification was completed on 2/13/13.
- Is Corrective Action Effective? Yes
- Corrective Action Verification Completion Date: 03/21/2013

Example 2 – Finding Details

- Project X does not ensure that dissenting opinions are handled per the process defined in NPR 7120.5 as required per the contract.
  - NPR 8000.4A, 3.1.1.i: The manager of each organizational unit shall ensure that dissenting opinions arising during risk management decision making are handled through the dissenting opinion process as defined in NPR 7120.5D.

Example 2 – CA

CORRECTIVE ACTION

- Initial Action: Began revising the Project X Risk Management Plan (RMP) (Document X) to address dissenting opinions.
- Root Cause: The Project X RMP did not specifically address the handling of dissenting opinions per the process defined in NPR 7120.5.
  - Cause Code: Procedure inadequate
- Planned Action to Correct Root Cause: Section 7.0 in Revision A of the Project X RMP will include the following statement: "If a candidate risk is disapproved, a clear, concise rationale for rejection, including dissenting opinions, is documented within the ABC Subsystem RM tool."

Example 2 – CA (Cont'd)

CORRECTIVE ACTION (Cont'd)

- Estimated Corrective Action Completion Date: 04/01/2011
- Action to Correct Root Cause: Final revision of SMAP Radiometer RMP (SMAP-PROJ-PLAN-0011 Rev. A) has completed formal review and addresses the dissenting opinions in Section 7.0.
- Estimated Corrective Action Verification Completion Date: 04/08/2011

CORRECTIVE ACTION EFFECTIVENESS

- Verification: Section 7.1 has been revised to elaborate on dissenting opinions in accordance with NPR 7120.5 (see attached).
- Is Corrective Action Effective? Yes
- Corrective Action Verification Completion Date: 04/08/2011

Example 3 – Finding Details

- Purchase Orders placed to calibration service providers do not flow ISO 17025 requirements as required contractually.
  - PO XXXX to XXX Calibration Laboratory does not flow requirements for compliance to ISO 17025.
  - NOTE: Contractor calibration technician was interviewed and stated that if the customer does not flow the requirements to Calibrate to ISO 17025 or other specific calibration requirements then the contractor does not calibrate to those requirements.
  - Calibration Service Providers listed in Contractor's Approved Supplier List have no indication of Calibration Standards Certification, i.e. ISO 17025 etc. Examples include but are not limited to: XYZ Services, ABC Metrology, XXX Calibration Laboratory.

Example 3 – CA

- Containment Actions: No effect on product. All equipment has been serviced by calibration facilities in compliance with ISO/IEC 17025.
- Root Cause Determination: ISO/IEC 17025 not stated on POs.
- Root Cause Analysis Results: XXX Calibration Laboratory only uses calibration services in compliance with ISO/IEC 17025, however ISO/IEC 17025 is not stated on POs.

Example 3 – CA (Cont.)

- Corrective/Preventive Action(s): XXX Calibration to document calibration services shall comply with requirements of ISO/IEC 17025 on all future POs. New PO 123456-789 for XXX Calibration Laboratory has documented the ISO/IEC 17025 requirement. QA shall assure this requirements is documented on all calibration service POs prior to sign-off and approval.
- Review of Corrective Action: Acceptable course of action, as long as verification of compliance is performed upon receipt of CoC.

Example 4 – Finding Details

- Rolls of Kapton tape were found in Building 123, Highbay area without any identification or shelf life indication.
  - Rolls of tape were used to hold protective foam pads in place on the Satellite panels. Step 1.2.3 speaks to use of the tape, but does not specify the type of tape and the tape used did not contain a part number for traceability.
  - No procedure could be found that addressed how the contractor assigns part numbers to materials such as Kapton tape or the tape mentioned above.

Example 4 – CA

- Containment Actions: Area was assessed to ensure there was no other unidentified material.
- Root Cause Determination: Engineer forgot to remove tape which was used on GSE Handling Frame after completing task. There is command media which documents control of materials.
- Root Cause Analysis Results:
  - 1) Root Cause for tape without any identification or shelf life: Roll of Kapton tape was used by engineer as non-flight hardware to wrap reflective mylar around the GSE Handling Frame for thermal reason per the test procedure. Engineer forgot to remove from highbay after completion of prep work and placed tape roll in container with other non-flight hardware.
    - Tape was originally contained in sealed bag with identification printed on bag. Bag was cut and discarded after tape was used and, therefore, any identification of tape material was lost as a result.

Example 4 – CA (Cont.)

- Root Cause Analysis Results (Cont'd):
  - 2) Root Cause for no procedure: Contractor documents require the review and approval of controlled support materials (CSM) by Engineering for compatibility with hardware and process. While there is no direct reference regarding how part numbers are assigned to CSM the detailed references included herein describe the control of CSM and how they should be documented.

Example 4 – CA (Cont.)

- There are Engineering documents related to the definition and documentation of controlled support material (CSM):
  - From X from, Materials and Processes Engineering Guidebook, Rev 0:
    - X. Controlled Support Material: A controlled support material (CSM) is a material that does not become part of the end-item, but is used in or around flight hardware and is necessary for accomplishing a process or operation during manufacture, assembly, integration, or test. M&P Engineering is responsible for evaluating the compatibility of CSMs with flight hardware. M&P Engineering also reviews the usage of CSMs in particular Manufacturing Process Instructions (MPI) for application-specific requirements.
  - From Paragraph Y of, Parts, Materials and Processes (PMP) Document Guidebook, Rev 2:
    - Y. Controlled Support Materials: Controlled support materials are materials invoked by the process specification that do not become part of the deliverable hardware. A "controlled support material" is also known as a "process consumable material." In this section all controlled support materials will be listed; the controlling specification, material code, and description will be included. Elsewhere in the specification the materials may be referenced by unique material code. If there are no controlled support materials, list "not applicable."

Example 4 – CA (Cont.)

- There are Product Support Engineering procedures related to the definition and call out of controlled support material (CSM):
  - From Paragraph X.1 of Manufacturing Work Instructions (MWI):
    - X.1: Support Materials that Contact Flight Hardware: Support materials that are used in flight hardware environments, but are not directly required by any drawings, material process specifications, or Manufacturing Process Instructions (MPIs), shall be approved by Engineering for compatibility. Materials used for shop aids, fixtures, and tools that come into contact with flight hardware shall be compatible with the flight hardware and subsequent processing.
    - Notes: Approved support materials are also known as Controlled Support Materials or shop supplies. Examples of such materials include solvents, cleaners, electrostatic discharge (ESD) protective items, applicators, clean room supplies, temporary hold-down tape, ultrasonic testing gel, thermal grease, and various other shop supplies. These support materials can be added to the Manufacturing Bill of Materials (MBOM) as required.

Example 4 – CA

- Corrective/Preventive Action(s):
  - 1) Corrective action for no procedure: None required. There is a procedure which documents control of materials.
  - 2) Corrective Action for tape without any identification or shelf life:
    - The Satellite Program decided they did not want to fund updating their Solar Array Panel Test Procedure. To help ensure that Test Procedures include part numbers of the tape that is intended to be temporarily used on flight hardware, the test manager included this item in the Lessons Learned review process.
- Review of Corrective Action: Not yet completed.

Example 5 – Finding Details

- Contractor does not have an ESD Control Plan applicable to the receiving dock or stockroom.
  - The manager of the area stated that he is "not aware of any requirement for any receiving dock or stockroom to have a ESD Plan." In response to an earlier NASA assessment, Contractor stated that:
    - "The ESD control plan referred to in Document X is referring to a Program specific ESD plan. The intent of CM document is for each program to develop a specific ESD plan for that program's specific ESD requirements. The ESD plan referred to is/was not intended specifically for the Stockroom."
  - ESD Protection is applicable throughout the processing of the hardware. This is similar to Card #015 which was issued during the previous assessment.

Example 5 – CA

- Containment Actions: No effect on product, as all the building's stockroom personal have successfully completed the ESD certification class and all employees certification's were up to date at the time of the audit.
- Root Cause Determination: Once the audit finding was identified, the team realized it was valid and starting working on it's solution. No formal root cause analysis was warranted.
- Root Cause Analysis Results: None.

Example 5 – CA (Cont.)

- Corrective/Preventive Action(s):
  - 1) Inventory Management developed a guide document for the protection of electrostatic discharge sensitive (ESDS) devices. The guide is Doc X and is located at the following link:
    - https://docX.…
  - 2) Inventory Management contacted Parts Material and Processing engineering (PMP). PMP reviewed the referenced document and completed a physical walk through of the building's ESD area. Both were found satisfactory.

Exercise Wrap-up Discussion

- Questions to ask yourself when generating or reviewing CAs:
  - Are identified causes addressed in responses?
  - Have causes been provided? Did you get to the root of the issue?
  - Is the scope investigation included and does it appear to be sufficient?
  - Have interim plans been put in place to mitigate immediate concerns?
  - Have ECDs been assigned to the CA actions?
  - Does the CA incorporate corrective actions that will prevent recurrence in the long-term or just provide a short term improvement in awareness?
  - Was effectiveness of the CA evaluated?

Forrest Reed

- EaglePicher Presentation: Corrective and Preventive Actions, Suppliers' Perspective
  - A supplier's story of improving corrective actions.

Wrap-up Discussion

Wrap-up Discussion

- Think about the amount of effort and resources that go into being audited.
- Think about the amount of effort and resources that go into auditing your organization and your suppliers.
- Now think about how your organization responds to internal and external audit findings – do you think they adequately investigate and address findings?
- Now think about how your suppliers respond to audit findings – do you think they are preventing recurrence with their response to audit findings?

Wrap-Up Discussion

- Do you think the gain of the audits is worth the pain (resources/effort/etc.)?
  - If yes, why? What works well for you?
  - If no, why? What needs improvement?
- How much could we improve the value of our audit programs with effective corrective and preventive actions – at the process level?
- How much could organizations improve if they focused on preventive actions?

Wrap-up Discussion

- Why do you think the CAs being submitted are not meeting the requirements?
  - Review Parking Lot
  - Others?
- For audit POCs in the room, what are your review processes for CAs prior to submission?
- Do the personnel responsible for submitting the CAs have authority to request additional information from CA owners if the CAs do not meet the requirements?
- What are the consequences for not meeting the CA requirements?
- Does anybody feel they have an effective process for establishing CAs at their organization?
- What actions can the community take to improve corrective action responses?

Questions?

Backup Slides

Other Examples

Example 6 – Finding Details

- Out of approximately 150 IM&TE that were inspected, the following IM&TE were found to be past their calibration interval:
  - ECN 70-20, helicoid test gauge (calibration due Feb. 20, 1986)
  - ID No. 190, tester full pressure suit (calibration due Jan. 10, 2006)
  - C453125, S/N 44, hose pressure test gage (calibration due Aug. 07, 2009)
  - ECN 787859, torque wrench (calibration due Aug. 7, 2009)
  - ECN C65573, torque wrench (calibration due Aug. 7, 2009)
  - ECN M625852, Sky D test set (calibration due Jan. 7, 2009)
  - ECN C45546, Sky D test set (calibration due Jan. 7, 2009)
  - ECN M654867, pressure gauge (calibration due Jun. 10, 2004)

Example 6 – CA

- Cause Category: Operational Controls
- Contractor X has added a verification step when IT&ME are being sent back to the Cal Rep after calibration. They now have a second person verify that proper labels are on the equipment. Procedure X will be updated to reflect this change. ECD 3/14/10
- Discuss this issue in Branch meetings. Discuss in weekly staff meeting. This issue has been brought up in the daily meetings several times already. This is to ensure that employees know to look at the cal label prior to using the equipment. ECD 3/25/10
- Does this CA meet the requirements?
- Is it adequate?
- What additional items should be addresses/evaluated?

Example 7 – Finding Details

- The shelf-life (SL) of materials used to manufacture and repair flight hardware is being extended without technical justification and against manufacturer recommendations.
  - Expired Primerless Silicon Firewall Sealant was observed being used on [aircraft] Engine Core Cowl (Work Number 45201). The sealant had a Mix/Fill Date of 5-12-08 and an expiration date of 11-12-08 on the package. The package also states that the SL is 6 months from the mix/fill date when stored at ambient temperature. The foil package that the material was packaged in also had a label indicating that the SL had been extended to 31 Jul 2010. No evidence could be provided that the extension of the SL was approved. The material manufacturer was contacted during the audit and they indicated that the SL could not be extended for the material. The technical adequacy (i.e. firewall sealing properties) are in question due to the use of the expired firewall sealant.

Example 7 – Finding Details (cont'd)

- Discussions with Center personnel indicated that SL extensions have been granted without technical justification upon requests from the crew chiefs. The Type of SL (I or II) is not being considered and extensions for Type II materials have been extended for greater than the 50% or the original SL as allowed by NPR 4100.1. Numerous materials have had extensions granted.
- NOTE: Conflicting requirements were noted on the Material Datasheet.

Example 7 – CA

- Cause Category: Operational Controls
- Work with organizations that have critical uses to determine extension policy (Preliminary decision to adopt modified DOD policy) (ECD: 1/30/10)
  - Which, if any chemicals will be extended
  - Maximum extension length (mfgr's recommendations or other)
  - Who has authority to approve extensions
  - Criteria to be used to determine if a chemical should be extended (DOD?)
  - Determine if we can do any physical testing here at the Center
  - Involve Operations Engineering in SL extension decisions – how
- Work with other organizations on extension policy for non-critical uses and appropriate SL labeling ECD 1/30/10

Example 7 – CA (Cont'd)

- Correct outstanding chemical issue – recover what we can and then remove all lost chemicals from database ECD 2/17/10
- Positive enforcement of the 48-hour return rule • Notification to users, then escalation • Ensure no chemicals are allowed to go to users homes ECD 1/2/10
- Revise procedure to provide:
  - Clear distinction between critical and non-critical uses and between Type I and II chemicals
  - Guidance on establishing container SL labeling
  - Center definitions of Type I and II with guidance for applying this classification to SL extension situations
  - Policy to turn in old chemical issues before obtaining new chemicals

Example 7 – CA (Cont'd)

- Revise procedure to provide (cont'd):
  - Revision, where needed, of procedure for tracking SL and notifying customer
  - Clear policy that when a material custodian identifies a chemical nearing its SL, the appropriate Zones must submit an extension request form or all use of the chemical will expire and all outstanding volumes must be returned to the material custodian • SL extension technical evaluation criteria (preliminary assumption is that we will adopt modified DOD criteria) • Revision of the extension request form as appropriate, e.g. signatures, application of extension criteria, etc. ECD 6/30/10
- Review all existing chemicals, establish shelf-life, 100% enforce procedure for SL ECD 6/30/10

Example 8 – Finding Details

- Waivers/deviations do not have requisite approvals and the Center procedure that defines the waiver process does not meet NPR 7120.5D requirements for Technical Authority (TA) approval (Engineering or SMA) of waivers.
  - Center Documents do not specify that TA approval is required for waivers/deviations to TA owned requirements.
  - Of the 5 deviations/waivers reviewed, none of them had the requisite approvals.

Example 8 – CA

- Cause: Waivers/Deviations data requirements and approval process not sufficiently defined. Compliance verification not required. Cause Category: Operational Controls
  - Level 2: Lack of adequate controls Level 3: Procedures inadequate
  - Level 2: Management review issues Level 3: Management inaction
  - Level 2: Process Definition Issue Level 3: Process/procedure outdated
- Revise Center requirements for Waivers/Deviations data and approval process that includes compliance verification. Incorporate Waivers/Deviations into the Center PRACA tool to ensure closed-loop reporting. ECD: 7/31/10

Example 9 – Finding Details

- Several projects were found not to have software assurance plans and software safety plans.
  - There were no Center baselined software assurance plans found for the projects reviewed, including A-1 Datamax, E-2 Data Processing, and E-2 Chemical Test. Additionally, a software safety plan was not found for the E-2 Chemical Test. The lack of software assurance and software safety plans can result in software assurance and software safety activities being implemented inconsistently or incompletely.

    However, draft software assurance and safety plans are actively being developed for two projects.

Example 9 – CA

- Cause: Projects are consistently not identifying Software Assurance or Software Safety Plans in their requirements, resulting in inadequate resources. This is due to unfamiliarity with the requirements listed in NPR 7150.2, NASA Software Engineering Requirements and to insufficient civil servant work force dedicated to software activities. This was noted in Finding 024 the Office of Chief Engineer's survey conducted in April 2009. For Projects that did request plans, resources within SMA were not available to complete the plans, such as the Rocket Propulsion Testing (RPT) Common Data Acquisition System (DAS) software project that is currently being led by the Center.
  - Cause Category: Strategic Management

Example 9 – CA (cont'd)

- Immediate Action: 1) The software assurance and software safety plans that are being drafted for the two projects will be completed. 2) A1 Datamax: The project is complete. No action will be taken. 3) E-2 Data Processing: Shortly after the QAAR audit was conducted, a Software Assurance Plan (Provider) was approved for the Data Operations Processing project. The project has deemed that the Acquirer software plan will not be written and that they are planning to write an Center Key Decision Record (KDR) DDMS to document this. This decision will require a variance (waiver). 4) E-2 Chemical Steam Generator (CSG): The project has stated that software plans are not required for this project based on the fact that current data acquisition and control systems will be used.

Example 9 – CA (cont'd)

- Scope Investigation: Plans are not in place with any of the projects other than Space Shuttle Main Engine (SSME) and ITS-ARTS Software (Provider) Assurance Plans. Open Projects without both Acquirer and Provider Plans are E-3 Subscale Diffuser, A1/A2 J-2X, and Cryogenic Transfer Facility.
- Corrective Action: ECD 10/16/11
  - Software assurance and software safety plans will be generated for the projects X and Y.
  - Project directorate will evaluate the requirement for plans for E-3 Subscale Diffuser, A1/A2 J-2X and Cryogenic Transfer Facility and ensure plans are written as required.

Example 9 – CA (cont'd)

- Corrective Action (cont'd): ECD 10/16/11
  - The Center's Software Working Group funding for FY 2011 will fund an effort to develop a generic site-wide Software Assurance and Safety Plan that will be generated for all projects to use as a starting point for developing these artifacts.
  - Project directorate personnel will be given training to ensure knowledge of software assurance and software safety requirements listed in NPR 7150.2.

Example 5 – Finding Details

- The current Electrostatic Discharge (ESD) training program does not include a recurrent training element as required by ANSI/ESD S20.20.
  - Center document for ESD training does not require recurrent training. Initial training only satisfies the current program requirements for ESD training and there is no discussion requiring a recurrent training at any defined intervals.
  - ANSI/ESD S20.20 section 7.2 states: "Initial and recurrent ESD awareness and prevention training shall be provided to all personnel who handle or otherwise come into contact with ESDS items."

Example 5 – CA

- Cause: Lack of funding for a replacement online ESD course was the root cause of the nonconformance. Prior to the audit, personnel had already initiated discussions (including funding) about a replacement online ESD certification training course. A two-year recertification requirement is slated to be added to the in-house ESD document. The current ESD certification training course is not adequate to handle the large number of individuals (350-450) that will need recurrent training once the recertification requirement is added to the requirements document. Therefore, efforts are focused on obtaining the replacement ESD certification training course prior to adding a new requirement.

Example 5 – CA (Cont'd)

- Corrective Action: ECD 1/13/12
  - Continue efforts toward the establishment of a replacement online ESD certification course. Once the online course is in place, the recertification training requirement can be added to the Center requirements document. The Center has already completed the reviews of two (2) web-based ESD training courses. The vendors allowed the Center to borrow demos of their ESD training products for evaluation. Two additional requests have been initiated for training demos from different vendors, as well. The Center training organization informed the personnel working on the course procurement that a minimum of four (4) quotes were needed. Once the reviews of all demo products have been completed, the replacement ESD training course will be selected. Note proposed completion date is contingent upon funding.

Other Root Cause Analysis Techniques

Different Approaches to Determining Cause

Failure Mode and Effects Analysis

Failure Modes and Effects Analysis (FMEA) Form

Organization:
Process:
Problem:
Prepared By:

Severity (SEV): How severe is the effect on the customer? (5 = Most Severe, 1 = Least
Probability of Occurrence (OCC): How often does the cause or FM occur? (5 = Highest Occurrence, 1 = Lowest Occurrence)
Detectability (DET): How well can you detect the cause or FM using current controls? (5 = Most Difficult to Detect, 1 = Easily)
Risk Priority Number (RPN): What is the measure of process risk related to the effects, causes & controls? (RPN = SEV. x OCC

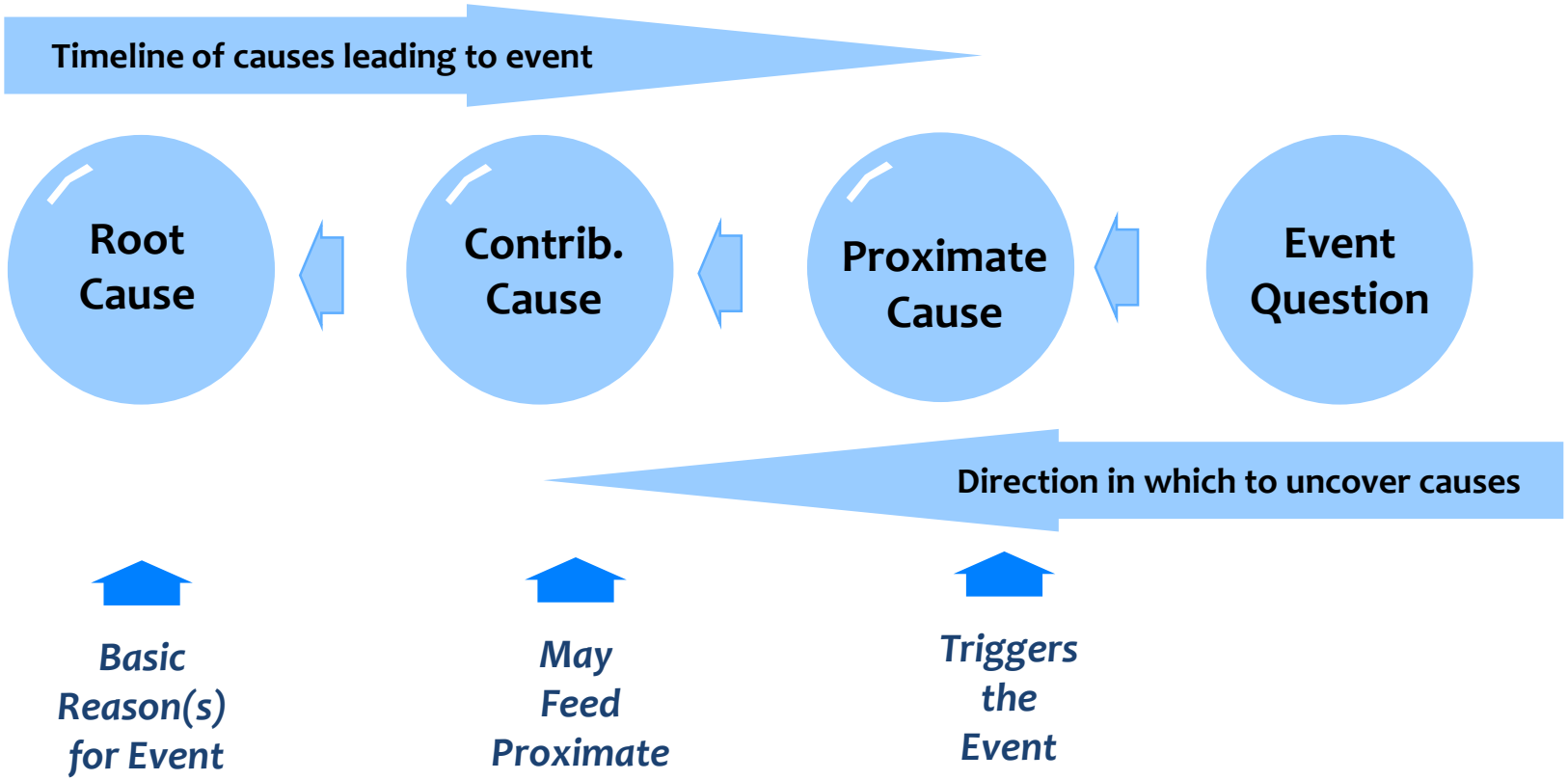
Process Step/Input (What is the process step/input?)	**Potential Failure Mode** (What can go wrong with the process step/input?)	**Potential Failure Effects** (What is the impact on the customer (output variables) or internal requirements?)	**SEV**	**Potential Causes** (What are the root cause reasons for the process step/input to go wrong?)	**OCC**	**Current Controls** (What are the existing controls that prevent or detect either the cause or the FM prior to leaving the process step?)	**DET**	**RPN**	**Actions Recommended** (What are the actions for reducing the OCC. of the cause or improving DET.?)	**Plans / Responsibility** (What is the target completion date and who is responsible?)	**pSEV**	**pOCC**	**pDET**

- Define the process step that led to the failure mode (Undesired Outcome)
- Identify Potential Causes
- Consider what controls are in place to mitigate or prevent either the Cause or the Failure Mode from occurring
- Define and implement actions to address causes

Additional CA Input

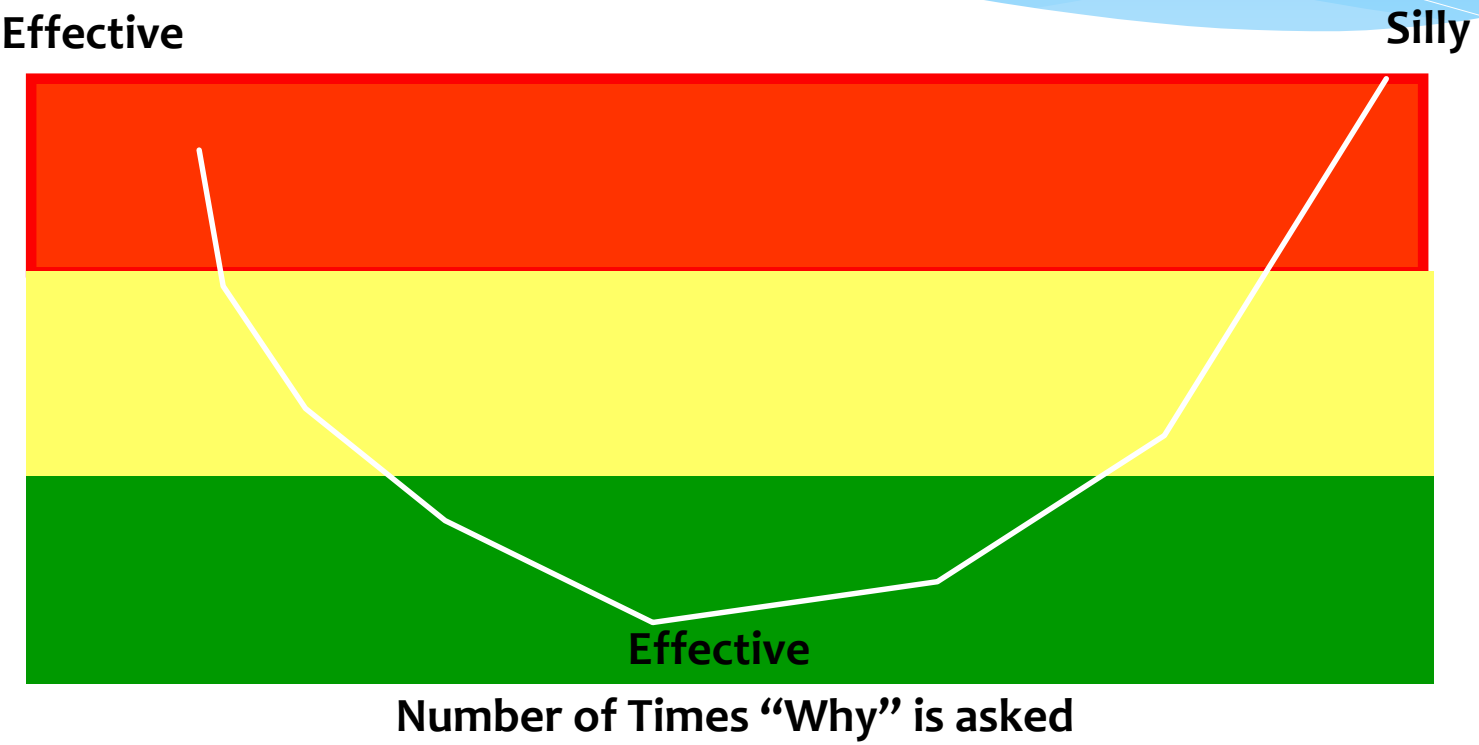
CA Components

- Root Cause Analysis Process (Cont'd)



CA Components

- Root Cause Analysis Process (Cont'd)



- Simply ask "Why" a sufficient number of times to understand the cause(s) behind the problem

CA Requirements

- Per NASA Policy Directive (NPD) 8730.5, paragraph 1.b(8), NASA Quality Assurance Programs shall:
  - Provide for investigative and corrective actions upon discovery or notification of noncompliance.
    - (a) Investigative actions shall identify the proximate and root cause(s) of noncompliance and the scope/population of noncompliant items.
    - (b) Corrective actions shall include the correction, replacement, repair, or authorized disposition of noncompliant items/conditions, implementation of preventive measures to eliminate the causes of noncompliance, and validation that implemented preventive measures have effectively eliminated recurrence of the noncompliant condition (recurrence control).

CA Requirements

- Per ISO 9001:2008 and AS9100C, sections 8.2.2 and 8.5.2:
  - (8.2.2 – Internal Audit) The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.
  - (8.2.2 – Internal Audit) Follow-up activities shall include the verification of the actions taken and the reporting of verification results.
  - (8.5.2 – Corrective Action) The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

CA Requirements (Cont.)

- Per ISO 9001:2008 and AS9100C, section 8.5.2 (Corrective Action):
  - A documented procedure shall be established to define requirements for
    - a) reviewing nonconformities (including customer complaints),
    - b) determining the causes of nonconformities,
    - c) evaluating the need for action to ensure that nonconformities do not recur
    - d) determining and implementing action needed,
    - e) records of the results of action taken (see 4.2.4),
    - f) reviewing the effectiveness of the corrective action taken,
    - ***g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,***
    - ***h) specific actions where timely and/or effective corrective actions are not achieved, and***
    - ***i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.***

CA Requirements (Cont.)

- There are other requirements in ISO 9001:2008 and AS9100C that tie into corrective action responses:
  - Section 8.2.3 (Monitoring and Measurement of Product).
    - When planned results are not achieved, correction and corrective action shall be taken, as appropriate.
    - Includes specifics on what to do when it is a process nonconformity including evaluation for product nonconformity
  - Section 8.3 (Control of Nonconforming Product)
  - Section 8.5.3 (Preventive Action)

Preventive Action Requirements

- Per ISO 9001:2008 and AS9100C, section 8.5.3 (Preventive Action):
  - A documented procedure shall be established to define requirements for
    - a) determining potential nonconformities and their causes,
    - b) evaluating the need for action to prevent *occurrence* of nonconformities,
    - c) determining and implementing action needed,
    - d) records of results of action taken (see 4.2.4), and
    - e) reviewing the effectiveness of the preventive action taken.